CEEMET
Council of European Employers of the Metal, Engineering and Technology-based industries

ORGALIME
Speaking for European engineering

Draft proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (optical radiation)

([19]th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

FINAL CEEMET AND ORGALIME COMMENTS
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INTRODUCTION

While CEEMET and ORGALIME acknowledge ICNIRP's independence and scientific expertise, which includes all disciplines necessary for non-ionizing radiation protection, we underline that ICNIRP's expertise is "*brought to bear on addressing the important issues of possible adverse effects on human health of exposure to non-ionising radiation*"[1], and not to supplement policy makers in their responsibility for establishing rules appropriate to each industrial and economical context. Such elements would have been provided by a detailed impact assessment for this new Directive and would have shed light on the policy choices to be proposed by the European Commission and discussed by the Council and the Parliament.

In particular, unlike for electromagnetic fields, there is no scientific uncertainty with regard to the risks for the eye or the skin that derive from exposure to optical radiations. Therefore, the risk assessment is carried out without incorporating additional safety margins by measure of precaution, just as for assessing the risk to have one's hand cut by a knife, given its sharpness and applied pressure.
The manufacturer of a machine tool that emits optical radiation already carries out an adequate risk assessment, which takes into consideration the realistic conditions of use and foreseeable misuse of such a machine by the operator, or make use of existing standards under the directives 98/37/EC (Machines safety) or 73/23/EEC (Low Voltage) that gives him the presumption of conformity to essential requirements on optical radiation for their very product category. The necessary safety and protective devices and training are provided in accordance with the legally binding "essential requirements" on optical radiation in the context of the Low Voltage Directive (73/23/EEC) and the Machinery Directive (98/37/EC).

Consequently, **in the absence of an appropriate impact assessment, Ceemet and Orgalime call on Member State representatives to take due consideration of the practical occupational conditions as well as already existing product related health and safety legislation and corresponding standards**.

Especially for laser technology, adequate protective devices and procedures have already been put in place at the worldwide level by application of the existing standards of the International Electro-technical Committee (IEC), and have proven their efficiency:

- ➔ IEC 60825-2 (2004-06) Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS)
- ➔ IEC/TR 60825-9 (1999-10) Safety of laser products - Part 9: Compilation of maximum permissible exposure to incoherent optical radiation
- ➔ IEC 60825-12 (2004-02) Safety of laser products - Part 12: Safety of free space optical communication systems used for transmission of information
- ➔ IEC/TR 60825-14 (2004-02) Safety of laser products - Part 14: A user's guide

Should the Council choose diverging limit values for an additional and, in our view, costly and superfluous risk assessment under the responsibility of the employer, it will further jeopardize industry's ability to stay competitive at world level and to supply jobs in Europe, without additional benefit for workers' protection.

[1] http://www.icnirp.de/what.htm

DRAFT PROPOSAL AS AT 21 SEPTEMBER 2004	CEEMET / ORGALIME COMMENTS	JUSTIFICATION
ARTICLE 4 – DETERMINATION OF EXPOSURE AND ASSESSMENT OF RISKS		
1. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer, in the case of workers exposed to artificial source of optical radiation, shall assess and, if necessary, measure and/or calculate the levels of exposure to optical radiation to which workers are likely to be exposed so that the measures needed to restrict exposure to the applicable limits can be identified and put into effect. The methodology applied in assessment, measurement and/or calculations shall follow the standards of IEC in respect of laser radiation and the recommendations of CIE and CEN in respect of non-coherent radiation. In exposure situations which are not covered by these standards and recommendations, and until appropriate EU standards or recommendations become available, assessment, measurement and/or calculations shall be carried out using available national or international science-based guidelines and also take account of data provided by the manufacturers of the equipment where it is covered by a relevant Community Directive.	1. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer, in the case of workers exposed to artificial source of optical radiation, shall assess and, if necessary, measure and/or calculate the levels of exposure to optical radiation to which workers are likely to be exposed so that the measures needed to restrict exposure to the applicable limits can be identified and put into effect. The methodology applied in assessment, measurement and/or calculations shall follow the standards **of CENELEC** in respect of laser radiation and the recommendations of **IEC** and CEN in respect of non-coherent radiation. In exposure situations which are not covered by these standards and recommendations, and until appropriate EU standards or recommendations become available, assessment, measurement and/or calculations shall be carried out using available national or international science-based guidelines and **be based on** data provided by the manufacturers of the equipment where it is covered by a relevant Community Directive. **Where such data is not available the assessment shall be based on existing published data.**	The machinery (98/37/EC) and low voltage (73/23/EEC) directives require manufacturers of equipment to provide users with relevant information on risk inherent to the use of the equipment, according to harmonised European standards under these directives, or according to the risk assessment they would have performed. This amendment will ensure that this data is used to inform the users risk assessment process. Where equipment is in use which pre-dates these directives light 'output' data should be used from published sources. This will enable the employer to comply with their responsibilities without excessive cost

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2. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer, in the case of workers exposed to natural sources of optical radiation, shall make an assessment of the risk to health and safety so that the measures needed to minimize these risks can be identified and put into effect. [..]		
3. The assessment, measurement and/or calculations referred to in Article 4(1) and the assessment referred to in Article 4(2) shall be planned and carried out by competent services or persons at suitable intervals, taking particular account of the provisions of Article 7 and Article 11 of Directive 89/391/EEC concerning the necessary competent services or persons and the consultation and participation of workers. The data obtained from the assessments, including that obtained from the measurement and/or calculations of the level of exposure referred to in Article 4(1) shall be preserved in a suitable form so as to permit consultation at a later stage.		

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4. Pursuant to Article 6(3) of Directive 89/391/EEC, the employer shall give particular attention, when carrying out the risk assessment, to the following: a) the level, wavelength range and duration of exposure to artificial sources of optical radiation; aa) [..] the duration of exposure to natural sources of optical radiation; b) the exposure limit values referred to in Article 3 of this Directive; c) any effects concerning the health and safety of workers **belonging to particularly sensitive risk groups;** **ca) any possible effects on workers' health and safety resulting from workplace interactions between optical radiation and photosensitive chemicals;** d) any indirect effects **like blinding, explosion or setting on fire**; e) the existence of replacement equipment designed to reduce the levels of exposure to optical radiation;	**4 a) to g) should be deleted.**	These requirements only serve to add complexity and cost to the duty. There is no impact assessment available for the cost of placing these duties on business.

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f) appropriate information obtained from health surveillance, including published information, as far as possible; g) multiple sources of exposure to optical radiation; h) a classification applied to a laser as defined in accordance with EN 60825-1 and, in relation to any artificial source likely to cause damage similar to that of a laser of class 3B or 4, any similar classification; i) information provided by the manufacturers of optical radiation sources and associated work equipment in accordance with the relevant Community Directives.		
5. The employer shall be in possession of an assessment of the risk in accordance with Article 9(1)(a) of Directive 89/391/EEC and shall identify which measures must be taken in accordance with Articles 5 and 6 of this Directive. The risk assessment shall be recorded on a suitable medium, according to national law and practice; it may include a justification by the employer that the nature and extent of the risks related to optical radiation make a further detailed risk assessment unnecessary. The risk assessment shall be updated on a regular basis, particularly if there have been significant changes which could render it out-of-date, or when the results of health surveillance show it to be necessary.		

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ARTICLE 8 - HEALTH SURVEILLANCE		
1. Without prejudice to Article 14 of Directive 89/391/EEC, Member States shall adopt provisions to ensure the appropriate health surveillance of workers with reference to the outcome of the risk assessment provided for in Article 4[..] of this Directive where it indicates a risk to their health. Those provisions, including the requirements specified for health records and their availability, shall be introduced in accordance with national law and/or practice.	1. Without prejudice to Article 14 of Directive 89/391/EEC, Member States shall adopt provisions to ensure the appropriate health surveillance of workers with reference to the outcome of the risk assessment provided for in Article 4(1) of this Directive where it indicates a **chronic** risk to their health. Those provisions, including the requirements specified for health records and their availability, shall be introduced in accordance with national law and/or practice.	The purpose of this duty should be to address those very small number of workers who may be at risk of developing cataracts as a result of exposure to infra-red radiation e.g. steel & foundry workers.
2. Member States shall establish arrangements to ensure that, for each worker who undergoes health surveillance in accordance with paragraph 1, individual health records are made and kept up-to-date. Health records shall contain a summary of the results of the health surveillance carried out. They shall be kept in a suitable form so as to permit any consultation at a later date, taking into account any confidentiality. Copies of the appropriate records shall be supplied to the competent authority on request, taking into account any confidentiality. The individual worker shall, at his request, have access to the health records relating to him personally.		

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3. Where, as a result of health surveillance, a worker is found to have an identifiable disease or adverse health effect which is considered by a doctor or occupational health-care professional to be the result of exposure to optical radiation at work: (a) the worker shall be informed by the doctor or other suitably qualified person of the result which relates to him personally. He shall, in particular, receive information and advice regarding any health surveillance which he should undergo following the end of exposure; (b) the employer shall be informed of any significant findings from the health surveillance, taking into account any medical confidentiality; (c) the employer shall: - review the risk assessment carried out pursuant to Article 4, - review the measures provided for to eliminate or reduce risks pursuant to Article 5, - take into account the advice of the occupational health-care professional or other suitably qualified person or the competent authority in implementing any measure required to eliminate or reduce risk in accordance with Article 5, including the possibility of assigning the worker to alternative work where there is no risk of exposure exceeding the appropriate ELV, and - arrange continued health surveillance and provide for a review of the health status of any other worker who has been similarly exposed. In such cases, the competent doctor or occupational health care professional or the competent authority may propose that the exposed persons undergo a medical examination.		